REMARKS

In the Office Action dated October 28, 2008, claims 1-4, 6, 7-10 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rasche et al. in view of Lang et al.

This rejection is respectfully traversed for the following reasons.

In the method and apparatus disclosed and claimed in the present application, a number of x-ray detectable markers are located in an anatomical environment of an implantable medical implant. The markers are spatially separated from the medical implant. The medical implant itself has x-ray detectable points thereon, which are different from the aforementioned markers.

In the method and apparatus disclosed and claimed in the present application, position changes of the implant are detected, by obtaining first and second 2D x-ray exposures respectively from first and second different projection directions of the region of the patient that contains the implant. The first and second 2D exposures are respectively obtained at temporally separated times, such that a positional change of the implant in the environment may have occurred between the time that the respective exposures are obtained. The aforementioned markers and the aforementioned points will have respective distributions in each of the first and second 2D exposures. If movement of the implant has occurred in the intervening time between the two exposures, these distributions will be different in the first and second exposures. From these first and second distributions in the respective exposures, a probability is automatically calculated as to whether the first and second distributions respectively represent the same three-dimensional distribution of the markers and the points. From this calculated degree of probability, a

determination is made as to whether a change in position of the implant in the environment has occurred.

In substantiating the rejection of independent claims 1 and 7 based on the Rasche et al. and Lang et al. references, the Examiner did not provide any specific citation for a teaching in either of those references to obtain two images, at separated points in time, of an implant and the anatomical environment thereof, for the purpose of comparing the distributions of the points and markers in these two separately-obtained images, in order to ascertain whether movement of the implant has occurred between the times that the respective images were obtained.

By contrast, in the Rasche et al. reference, a *simulated* image is compared with a real image. As stated in paragraph [0010] of the Rasche et al. reference, the real image can, in principle, be a single 2D image. In paragraph [0011], however, it is also noted that multiple projections can be used, in the conventional manner of computed tomography, to produce a slice image or a 3D image, which is then used as the aforementioned real image. Therefore, even though the Rasche et al. reference provides the possibility of obtaining multiple real time images, such as in the form of projections, these images are not obtained in Rasche et al. for the purpose of comparing them against each other, but only for the purpose of reconstructing the aforementioned real image therefrom, and it is then this reconstructed real image that is compared to the aforementioned simulated image. Since the simulated image bears no specific time relationship to the real image, it has no capability of being used to determine whether an implant has changed in position in the intervening time between a first image and a later-acquired second image. In the Rasche et al. method and apparatus, even if non-congruence exists,

between the identifiable markers in the simulated image and the real image, this only permits the conclusion to be made that the object under consideration, namely a surgical instrument, is not positioned in the real image at the "optimum" position that is represented by the simulated image. For the use of guiding a surgical instrument, this is useful information, but it would be completely irrelevant to determining whether movement of a surgical implant has occurred, because there is no time-correlation between the simulated image and any image of such an implant in the anatomical environment of a subject.

Therefore, as the Examiner has acknowledged, the Rasche et al. reference does not disclose undertaking a probability calculation to determine if the first and second distributions of the markers are in the same position. This is a true statement, but it is because, for the aforementioned reasons, undertaking such a probability calculation would serve no purpose in the Rasche et al. reference. Therefore, whether the Lang et al. reference does or does not disclose undertaking such a calculation, modifying the Rasche et al. reference in accordance with such (alleged) teachings of the Lang et al. still would not result in the method or system disclosed and claimed in the independent claims of the present application.

Applicants submit, however, that the Lang et al. reference does not disclose making such a probability calculation, for any purpose. The Lang et al. reference discloses methods, algorithms and devices for analyzing x-ray images, in particular to allow accurate and reliable evaluation of bone mineral and bone structure, as explained in the Lang et al. Abstract and as stated in claim 1 thereof. The passages cited by the Examiner merely represent a summary of general knowledge and non-specific information related to data manipulation, computer program products,

correction factors and anatomical landmarks. Such general information is not sufficiently detailed or specific so as to provide a teaching, guidance or motivation to a person of ordinary skill in the field of medical imaging analysis to modify the Rasche et al. reference in order to arrive at the subject matter of either of independent claims 1 or 7 of the present application.

Even if the teachings of Lang et al. were applied to the method or system disclosed in the Rasche et al. reference, despite any rationale for doing so, this would merely result in the general techniques disclosed in Lang et al. being used as the basis for comparing the simulated image with the real image. For the reasons noted above, such a comparison has no capability whatsoever of determining whether a medical implant has moved between two chronologically separated points in time. The most that the general teachings disclosed in Lang et al. could provide would be a technique to determine whether the surgical implant in the Rasche et al. reference is positioned in the optimal position represented by the simulation image. This is not the subject matter disclosed and claimed in the present application, and does not bear any relationship thereto.

For the above reasons, Applicants submit that none of claims 1-4, 6, 7-10 or 12 would have been obvious to a person of ordinary skill in the field of medical image evaluation, under the provisions of 35 U.S.C. §103(a).

Claims 5-11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rasche et al. and Lang et al., further in view of Allen.

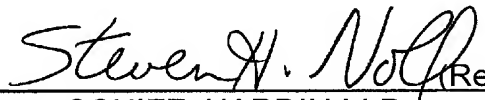
The above arguments are equally applicable to this rejection. In view of the deficiencies of the Rasche et al./Lang et al. combination, even if that combination

were further modified in accordance with the teachings of Allen, the subject matter of claims 5 and 11 still would not result.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



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